UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
Trenton

NOVO NORDISK INC., *et al.*, *Plaintiffs*, v. XAVIER BECERRA, *et al.*, *Defendants*.	No. 3:23-cv-20814-ZNQ-JBD

PLAINTIFFS' MEMORANDUM IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Government programs that dictate the prices charged for products sold in interstate commerce pose challenges for rule-of-law values and the Constitution's separation of powers. Choosing which products should be subject to government-dictated prices—and thus which manufacturers will be denied their common-law right to charge market-based prices—requires a careful exercise of legislative judgment. The choices that Congress makes must be protected from evasion or revision by executive branch officials. Similarly, dictating the prices that manufacturers may charge implicates important public interests and private rights. Because the public will be irreparably harmed if prices are set at levels that lead to shortages or undermine beneficial innovation, and because manufacturers are constitutionally entitled to a reasonable return on their investments, when Congress enacts a price-setting statute it must include both *standards* to cabin executive discretion and adequate *processes* to protect against the imposition of arbitrary or confiscatory prices. These constitutional safeguards are essential to ensuring lawful, transparent, and accountable government.

The actions taken by the Centers for Medicare & Medicaid Services ("CMS"), on behalf of the Secretary of the U.S. Department of Health and Human Services ("HHS"), to implement the Inflation Reduction Act of 2022 ("IRA") are unlawful because they violate the statute's plain text. Congress directed that price controls would be imposed in the program's first year on no more than 10 drug or biological products, and only on products that have been approved or licensed by the Food and Drug Administration

("FDA") for at least 7 years (in the case of drug products) or at least 11 years (in the case of biological products). CMS has violated these express statutory mandates by imposing price controls on aggregated *groupings* of products—comprising far more than 10 individual products—merely because the different products contain the same "active moiety" or "active ingredient" (terms that appear nowhere in the statute). By grouping products in this way, CMS is also trying to impose price controls on products that have not been approved or licensed for the requisite 7- or 11-year period. These and other deviations from the IRA's plain text far exceed CMS's delegated authority and result in departures from the IRA's statutory terms that are in conflict with decades of well-established FDA regulation and policy.

CMS is also disregarding express limits that Congress placed on the agency's authority to create and impose new substantive legal obligations. Recognizing that new requirements could burden manufacturers and harm patients' access to needed medications, the IRA instructs that CMS "shall" implement its provisions through "guidance" and *withholds rulemaking authority* from the agency until after the program has been in existence for at least 3 years. Violating that mandate, CMS seeks to impose new obligations on manufacturers as a condition of providing their drugs to patients in large segments of the nation's prescription-drug market. Those obligations go far beyond what is permissible in guidance because they operate as binding legal rules that cannot be imposed without complying with notice-and-comment procedures. Because CMS has not complied with those requirements, its "guidance" is unlawful.

CMS's statutory rewrite reinforces and exacerbates the IRA's grave underlying constitutional problems. Where, as here, a statute delegates broad authority to an agency to set prices, Congress must provide an intelligible principle to control the agency's price-setting decisions. Not only does the IRA fail to include any intelligible principle governing the prices set by CMS, it combines that sweeping delegation with other constitutional violations that blur lines of accountability and undermine the Constitution's essential structural protections. More specifically, the IRA lacks adequate procedures to protect against unfair and confiscatory pricing; attempts to strip the judiciary of the power to review CMS's highly consequential price-setting decisions; and imposes a compelled speech requirement that forces manufacturers to "agree" that any price imposed by CMS is the "maximum fair price," no matter how unreasonable, arbitrary, or unfair the price might be. No statute in this nation's history—not even during wartime—has delegated such broad and unchecked price-setting authority to an administrative agency and simultaneously stripped away so many constitutional safeguards necessary to protect individual rights and the broader public interest.

The Court should vacate CMS's guidance, strike down CMS's ultra vires actions imposing price controls on aggregated groupings of products manufactured by plaintiffs Novo Nordisk Inc. and Novo Nordisk Pharma, Inc. (together "Novo"), and direct CMS to comply with the statute as written by Congress. Granting complete relief should prevent CMS from applying the IRA to Novo. If that is not the case, the Court

should strike down the IRA in its entirety as an unprecedented departure from the Constitution's essential norms and structural guarantees.

BACKGROUND

A. Drug Pricing Before the Inflation Reduction Act

Relying on the ability to sell their products at market-based prices, manufacturers have invested billions of dollars in discovering, developing, and commercializing new medications and improving existing ones. They have made those investments because drug pricing in this country has historically been informed by market forces, which has allowed manufacturers to take on the monumental risks and seek to recover the staggering costs associated with pharmaceutical innovation.

Pharmaceutical manufacturers annually invest billions of dollars in research and development, conduct rigorous preclinical and clinical testing, and shepherd new and improved medications through a lengthy FDA-approval and licensing process, with no certainty that any new product will ever be approved, marketed, or sold. The average cost of bringing a single new product to market is estimated to be more than $2 billion, and the process takes an average of 10 to 15 years. *See* CBO, No. 57025, Research and Development in the Pharmaceutical Industry, at 14 (Apr. 2021); GAO, No. GAO-20-215SP, Artificial Intelligence in Health Care, at 34 (Dec. 2019). Only about 1 in 5000 potential products successfully navigates these hurdles—the vast majority are never approved. *See* Paula Carracedo-Reboredo et al., *A Review on Machine Learning Approaches and Trends in Drug Discovery*, 19 Computational & Structural Biotech. J. 4538, 4547 (2021).

Until now, the federal government has recognized that bureaucratic interference can increase costs and threaten the pace of development and innovation of therapies. Because the government acts as both a regulator and the "domina[nt]" market participant, *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699 (3d Cir. 2023), there is a recognized danger that the government will use price-setting procedures to further its own financial and parochial interests at the expense of private rights and the broader public interest. Medicare Part D's authors thus recognized that prohibiting agency officials from interfering with market-based prices was a "fundamental protection" necessary to prevent "price fixing by the CMS bureaucracy." 149 Cong. Rec. S15624 (daily ed. Nov. 23, 2003) (statement of Sen. Grassley).

These concerns have become more important as the government has taken over ever larger portions of the nation's healthcare markets. Medicare Part D, for instance, began as a comparatively small part of the nation's prescription drug market. That is no longer the case. About 53 million individuals are currently enrolled in Medicare Part D, and "Medicare Part D drug expenditures" have "exceeded $200 billion" per year. GAO, No. GAO-23-105270, Medicare Part D: CMS Should Monitor Effects of Rebates on Plan Formularies and Beneficiary Spending (Sept. 2023); *see also* Assistant Sec'y of Planning & Evaluation, Office of Health Pol'y, No. HP-2023-19, Inflation Reduction Act Research Series—Medicare Enrollees' Use and Out-of-Pocket Expenditures for Drugs Selected for Negotiation under the Medicare Drug Price Negotiation Program, at 2 (July 7, 2023). The government now dominates large swaths

of the market and accounts for "almost half the annual nationwide spending on prescription drugs." *Sanofi Aventis*, 58 F.4th at 699 (citing CBO, No. 57050, Prescription Drugs: Spending, Use, and Prices, at 8 (Jan. 2022)).

B. The Inflation Reduction Act

In August 2022, Congress enacted the IRA. In a stark deviation from historical practice, the statute's drug-pricing provisions direct CMS to impose price controls on an expanding number of manufacturers' prescription medications.

Recognizing that regulating prices for too many products all at once would cause massive upheaval, the statute expressly limits which products may be subjected to government-imposed prices. Congress mandated that, for 2026, CMS may set prices on only 10 drug or biological products. 42 U.S.C. § 1320f-1(a)(1), (e)(1). In 2027 and 2028, CMS may set prices on an additional 15 products per year. *Id.* § 1320f-1(a)(2), (3). And in 2029 and beyond, the statute authorizes price controls on an additional 20 products per year. *Id.* § 1320f-1(a)(4).

Congress also mandated that manufacturers would be stripped of their right to charge market-based prices only *after* a specified period of unburdened sales. Congress prohibited CMS from setting prices for any drug product approved for less than 7 years or any biological product licensed for less than 11 years. 42 U.S.C. § 1320f-1(e)(1). Congress also made clear that a drug or biological product may not be subject to price controls if it faces marketed generic or biosimilar competition. *Id.*

The statute provides clear instructions on how CMS should determine which products should be subject to price controls. Congress mandated which drug and biological products would be eligible for inclusion in the price control program, and then directed CMS to rank each eligible marketed drug and biological product according to Medicare's total gross expenditures. 42 U.S.C. § 1320f-1(b). In deciding which products meet the statute's high-spend requirement, the statute directs CMS to "use data" aggregated across certain specified product characteristics—in particular, across "dosage forms and strengths of the drug, including new formulations …, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug." *Id.* § 1320f-1(d)(3)(B). The statute does not authorize aggregation based on other features of a drug product.

Recognizing the risk that CMS would overstep in its implementation of the IRA, which could unfairly burden manufacturers and harm patients, Congress deliberately prohibited the agency from creating or imposing new substantive obligations with the force of law. Although the statute in other contexts instructs executive officials to "prescribe such regulations and other guidance as are necessary or appropriate to carry out … the purposes of this section," *see* Pub. L. No. 117-169, § 10201, 136 Stat. 1818, 1831 (2022) (amending § 4501(f)), the IRA withholds any authority for CMS to promulgate binding regulations for three years. Instead, the statute directs that CMS "shall implement this section … for 2026, 2027, and 2028 by program instruction or other forms of program guidance." *Id.* §§ 11001(c), 11002(c), 136 Stat. at 1854, 1862.

Despite carefully limiting CMS's rulemaking authority and which products are eligible for price controls, the IRA contains no meaningful standards to govern the "maximum fair prices" imposed by CMS. There is no statutory requirement that the prices be just and reasonable, or that CMS protect innovation or patient access, avoid shortages, or set prices at fair and non-confiscatory levels. The statute instead includes a breathtakingly expansive delegation for CMS to set prices at any level it chooses.

Rather than take responsibility for the consequences of its novel price-control regime, Congress ladened the IRA with provisions that blur lines of accountability. Most notably, the statute labels the price-setting process a "negotiation," suggesting that manufacturers have a meaningful say in the prices imposed. In fact, however, the process bears no resemblance to a "negotiation" in any sense of the term. The hallmarks of a true "negotiation" are that the parties have equal bargaining powers and neither party will be forced into a position it does not support. The "negotiation" contemplated by the IRA strays far from those basic requirements. Instead, the statute mandates that any manufacturer of a product targeted for price controls must disclose highly sensitive data that no manufacturer would voluntarily disclose. *See* 42 U.S.C. § 1320f-2(a); *see also* Hauda Decl. ¶¶ 55–59. After considering that information, CMS unilaterally proposes a price below a statutory ceiling, which can be no higher than 40% to 75% of the product's average price to non-federal purchasers. 42 U.S.C. § 1320f-3(c)(1)(C), (b)(2)(F); 38 U.S.C. § 8126(h)(5). Apart from this price ceiling, the statute contains no standard, methodology, or other instruction to guide CMS's price-setting

decision. The statute leaves the price to CMS's unfettered discretion, with nothing more than a suggestion to "ai[m] to achieve the lowest maximum fair price for each selected drug." 42 U.S.C. § 1320f-3(b)(1).

Manufacturers also have no reasonable or practical ability to escape the government's unilateral price controls. If a manufacturer refuses to sell at CMS's prescribed price, the manufacturer is punished with one of two untenable outcomes—either (1) paying a ruinous penalty indefinitely or (2) withdrawing *all* of its products from Medicare and Medicaid (even products not subject to CMS's price controls) after months of paying the penalty. 26 U.S.C. § 5000D(b)(1)–(4). The penalty—mislabeled an "excise tax"—accrues daily and can range from nearly double the product's daily sales revenue to up to *19 times* the product's total daily sales revenue. Cong. Rsch. Serv., No. R47202, Tax Provisions in the Inflation Reduction Act of 2022 (H.R. 5376), at 4 tbl. 2 (Aug. 10, 2022). A manufacturer can stop the penalty from accruing only by withdrawing *all* of its products from Medicare and Medicaid—which is practically impossible and would be devastating for Medicare and Medicaid patients. *See* Hauda Decl. ¶¶ 66–67, 77. As noted above, the federal government has taken control of nearly half of the nation's prescription drug market, and over a hundred million patients in the federal government programs depend on having access to manufacturers' drugs. Moreover, even if a manufacturer could withdraw all of its products from such a sizeable part of the market, it would still face months of daily penalties because the statute mandates that it takes 11 to 23 months after a manufacturer submits a notice for

a withdrawal to take effect. *See* 42 U.S.C. § 1395w-114a(b)(4)(B)(ii); 42 C.F.R. § 423.2345(b)(2); 42 U.S.C. § 1395w-114c(b)(4)(B)(ii).

The statute includes other provisions that further obscure lines of accountability. Perhaps most notably, the statute bars judicial review of many of the agency's most consequential decisions, including the agency's selection of which 10 drug or biological products to subject to price controls, its determination of which products meet the eligibility criteria to be classified as "qualifying single source drugs," and its determination of what price should be deemed "the maximum fair price." 42 U.S.C. § 1320f-7. In Orwellian fashion, the statute also forces manufacturers to agree publicly that CMS's imposed price is the "maximum fair price" or face crushing daily "excise taxes." 26 U.S.C. § 5000D.

C. CMS's Final Guidance

On June 30, 2023, CMS issued a 198-page "guidance" document. *See* CMS, Medicare Drug Price Negotiation Program: Revised Guidance (June 30, 2023) ("Final Guidance"). Given the IRA's unprecedented provisions—and the risks to patients, providers, and other stakeholders of disrupting the nation's healthcare markets and product-development pipeline—one would have expected CMS to take a modest approach. Instead, the agency's guidance goes far beyond announcing CMS's policy decisions and imposes substantial new binding obligations on manufacturers. *See id.* at 131–32.

First, the agency has eliminated the statute's careful limits on the number and types of products eligible for price controls. According to CMS, it is not limited to imposing price controls on only 10 drug or biological products, as the statute directs, but instead may dictate prices across entire families of products that contain the same *active moieties* (in the case of drug products) or the same *active ingredients* (in the case of biological products). Final Guidance § 30.1. CMS has thus transformed the IRA's provisions from a pricing scheme for drug and biological products into a pricing scheme for "active moieties" and "active ingredients"—and has disregarded the specific safety and efficacy analysis that must support product approval decisions. CMS's guidance also disregards essential statutory criteria by imposing price controls on products that were approved or licensed less than 7 or 11 years ago based on an earlier approval of a different drug product containing the same active moiety or a different biological product containing the same active ingredient. *See id.*

Second, the guidance purports to regulate products that the statute excludes from price controls. The IRA directs that CMS may not set prices for any product that is (1) the "reference listed drug" for any drug product that is "approved and marketed under section 355(j)" (commonly known as a generic drug) or (2) "the reference product for any biological product that is licensed and marketed under section 262(k)" (commonly known as a biosimilar). 42 U.S.C. § 1320f-1(e). That mandate reflects Congress's intent to deny CMS authority to impose price controls on products subject to marketed generic or biosimilar competition, since multi-source drugs already face

price pressure from competition. Nothing in the statute grants CMS authority to evaluate for itself the *quality* or *amount* of competition. Rather than staying within the statute's bounds, however, the agency will remove price controls only if a competitor engages in what CMS, in its sole discretion, deems to be "bona fide" marketing. Final Guidance § 30.1. The guidance asserts that CMS will "monitor" the market to determine, based on the "totality of circumstances," whether "meaningful competition" exists. *Id.* at 74 & § 90.4. Such an amorphous standard, which can be applied arbitrarily and inconsistently, is contrary to the IRA.

Third, the guidance imposes a host of other new substantive requirements found nowhere in the statute. For example, the guidance redefines the term "manufacturer" and divides it into two types of entities—a "primary manufacturer" and a "secondary manufacturer." Final Guidance § 40. While the statute defines "manufacturer" broadly to include any entity engaged in "the production, preparation, propagation, compounding, conversion, or processing of prescription drug products" or in the "packaging, repackaging, labeling, relabeling, or distribution of prescription drug products," 38 U.S.C. § 8126(h)(4)(B); 42 U.S.C. § 1320f(c)(1)., CMS's guidance defines a "primary manufacturer" as the entity that holds the new drug application ("NDA") or biologics licensing application ("BLA") for the selected drug and relegates all others to "secondary manufacturer" status. Final Guidance § 40. This artificial distinction has real consequences, as primary manufacturers are responsible under CMS's guidance for collecting data and monitoring compliance for secondary manufacturers, even though

critical pricing data is rarely shared between manufacturers for competitive and antitrust reasons. *See id.* §§ 40, 50.1, 90.2. In addition, the guidance imposes new data collection requirements, forcing manufacturers to submit large quantities of highly sensitive and confidential information not required by the statute. For instance, instead of requesting research-and-development costs, as the statute permits, CMS breaks this request down into five unique sub-elements, each of which includes additional definitions, instructions, and de facto sub-requirements that go beyond what the statute provides in its text. *See id.* App. C.

On August 29, 2023, CMS announced the products it plans to subject to price controls in 2026. In addition to at least 9 other distinct products, CMS identified 6 different products manufactured by Novo for which the agency intends to dictate a single price. In other words, while the IRA authorizes CMS to set prices on only 10 products, the agency has ignored that limit and subjected multiple Novo products to price controls that otherwise would not satisfy the IRA's criteria. Facing a crushing excise tax and unable to withdraw its entire portfolio of products from government healthcare programs, Novo had no option but to execute a "negotiation" agreement with CMS, while preserving its litigation rights. *See* CMS, Manufacturer Agreements for Selected Drugs for Initial Price Applicability Year 2026 (Oct. 3, 2023); Hauda Decl. ¶¶ 50, 52 & Exs. E, F.

STANDING

Novo has standing to challenge both CMS's actions and the IRA. Novo's standing is "self-evident" because its products are the direct "'object of the [agency] action … at issue.'" *Sierra Club v. EPA*, 292 F.3d 895, 900 (D.C. Cir. 2002) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561–62 (1992)). Novo faces at least four concrete and particular injuries, which are traceable to CMS and the IRA and would be redressed by granting the relief that Novo seeks.

First, because CMS has targeted six different Novo products for price controls, the company faces imminent injury by being forced to participate in an unfair and one-sided "negotiation" process and by being forced to sell its products at dictated prices. *See* Hauda Decl. ¶¶ 53–54, 62–70; *Horne v. Dep't of Agric.*, 576 U.S. 350, 363 (2015) (the government deprives a company of property when it demands property in exchange for a price "set at the government's discretion"). Novo contends that CMS's approach violates its statutory rights. *See Zivotofksy ex rel. Ari Z. v. Secretary of State*, 444 F.3d 614, 619 (D.C. Cir. 2006) (recognizing that a violation of an "individual right" conferred by a statute is a "concrete and particular injury for standing purposes").

Second, Novo faces the infringement of its constitutional rights, including its rights to due process and free speech. *See Spokeo, Inc. v. Robins*, 578 U.S. 330, 340 (2016) (such "intangible injuries" to constitutional rights satisfy the Article III injury-in-fact requirement). These constitutional injuries are ongoing and future constitutional

injuries are imminent unless the Court strikes down CMS's unlawful actions and the IRA's unlawful provisions.

Third, Novo has incurred and will continue to incur significant costs complying with CMS's requirements that it disclose highly sensitive and confidential trade secret and commercial information to CMS. *See* Hauda Decl. ¶¶ 61, 63; 42 U.S.C. §§ 1320f(d)(5)(A), 1320f-2(a)(4), 1320f-3(b)(2)(A); *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2204 (2021) ("If a defendant has caused … monetary injury to the plaintiff, the plaintiff has suffered a concrete injury in fact under Article III."); *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1003–04 (1984) (acknowledging that trade-secret information is property under the Constitution). Novo treats this information as highly confidential and would not ordinarily share it with the government or any other potential contracting partner.

Fourth, Novo faces an imminent financial injury if it tries to withdraw from CMS's price-setting scheme, either by being forced to pay a massive excise tax or by losing access to approximately half of the prescription-drug market for all its products. *See* Hauda Decl. ¶¶ 64–67; 26 U.S.C. § 5000D(b)(1)–(4), (c); 42 U.S.C. §§ 1396r-8(a)(1), 1395w-114a(b)(4)(B)(ii), 1395w-114c(b)(4)(B)(ii); *California v. Texas*, 141 S. Ct. 2104, 2114 (2021) (standing arises when an injury "is the result of a statute's actual or threatened enforcement, whether today or in the future" (emphasis omitted)).

LEGAL STANDARD

When "there is no genuine issue as to any material fact," summary judgment is appropriate if "the moving party is entitled to judgment as a matter of law." *Stepan Co. v. Callahan Co.*, 568 F. Supp. 2d 546, 549 (D.N.J. 2008). A reviewing court must set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

ARGUMENT

I. CMS's Actions Violate the Inflation Reduction Act's Express Mandates.

Because the "role" of a court is to apply a "statute as it is written," *Burrage v. United States*, 571 U.S. 204, 218 (2014), CMS's decision to subject at least 15 products—including 6 different Novo products—to price controls should not be allowed to stand. Because CMS's approach violates multiple express statutory mandates, the agency's ultra vires actions should be declared unlawful and vacated. *Am. Bankers Ass'n v. Nat'l Credit Union Admin.*, 934 F.3d 649, 673 (D.C. Cir. 2019) ("When a rule is contrary to law, the 'ordinary practice is to vacate' it."); *Ind. & Mich. Elec. Co. v. Fed. Power Comm'n*, 502 F.2d 336, 343 (D.C. Cir. 1974) (invalidating an ultra vires order).

A. CMS Has Unlawfully Imposed Price Controls on Products that Congress Specifically Excluded.

Determining what products are eligible for price controls—and which manufacturers must bear the burden of government-imposed prices—is a legislative function. *See Int'l Harvester Co. v. Missouri*, 234 U.S. 199, 215 (1914) ("determin[ing] upon what differences a distinction may be made for the purpose of statutory classification"

is "a matter of legislative judgment"). It is therefore essential that courts enforce the lines that Congress draws. Here, CMS has imposed price controls on far more products than Congress authorized and on products that Congress determined would not be subject to price controls. The result is an ultra vires regulatory scheme that violates the statute's express mandates, stymies innovation, and harms patients.

1. CMS's Approach Exceeds the Numerical Statutory Limit Mandated by Congress.

The IRA authorizes CMS to impose price controls on only 10 products in 2026, reflecting Congress's intent that CMS should dictate prices on a discrete number of products, which would expand gradually over time. 42 U.S.C. § 1320f-1(a); *Cf. RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) ("Congress [] enacted a comprehensive scheme and [] deliberately targeted specific problems with specific solutions."). CMS has violated the statute's clear and express mandate by imposing price controls on more than 10 products.

The IRA directs CMS to follow three steps in identifying which 10 "negotiation-eligible drugs" will be subject to price controls: *First*, CMS must identify "drug products" and "biological products" that have been either (1) approved by FDA under section 505(c) of the Federal Food, Drug, and Cosmetic Act ("FDCA") for at least 7 years (in the case of drug products) or (2) licensed by FDA under section 351(a) of the Public Health Service Act ("PHSA") for at least 11 years (in the case of biological products). *See* 42 U.S.C. § 1320f-1(e)(1)(A)(ii), (B)(ii). *Second*, CMS must eliminate any

product that faces competition because it is either a reference-listed drug or a reference product for a marketed generic drug or biosimilar product approved or licensed by FDA. *See id.* § 1320f-1(e)(1)(A)(iii), (B)(iii) (citing section 505(j) of the FDCA, 21 U.S.C. § 355(j) and section 351(k) of the PHSA, 42 U.S.C. § 262(k)). *Third*, CMS is required to "use data that is aggregated across dosage forms and strengths" to identify the top 10 high-spend products. *Id.* § 1320f-1(d)(3)(B).

Instead of complying with these express mandates, CMS has grouped together different products and subjected the entire grouping to price controls. With respect to Novo, the agency's "tenth" selection encompasses *six different biological products*—approved separately and at different times by FDA over two decades—as a single "negotiation-eligible drug." *See* Hauda Decl. ¶¶ 26–41, 47.

The selected drug list for the first round of negotiation is:

- Eliquis
- Jardiance
- Xarelto
- Januvia
- Farxiga
- Entresto
- Enbrel
- Imbruvica
- Stelara
- Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill

Press Release, HHS, *HHS Selects the First Drugs for Medicare Drug Price Negotiation* (Aug. 29, 2023). CMS accomplished this evasion of the statute's numerical restriction by lumping together all biological products by the same manufacturer that contain the same active ingredient and treating the aggregated grouping as a single selected drug.

See Final Guidance § 30.1. On that basis, CMS grouped together multiple Novo products because they share insulin aspart as an active ingredient: FIASP® vial (approved 2017), FIASP® FlexTouch (approved 2017), FIASP® PenFill (approved 2018), NovoLog® vial (approved 2000), NovoLog® PenFill® (approved 2000), NovoLog® FlexPen® (approved 2001).[1]

CMS cannot evade the statute's careful limit on how many products can be subjected to price controls—no more than 10—by deeming six different products a single selected drug based on the products' active ingredient. The approvals required for negotiation eligibility under the IRA are specific to individual drug or biological products. *See* 42 U.S.C. § 1320f-1(e)(1)(A)(i), (B)(i) (citing 21 U.S.C. § 355(c) and 42 U.S.C. § 262(a)). And the IRA says nothing about active moieties or active ingredients, and nothing authorizes CMS to dictate prices for groupings of products.

The Supreme Court rejected CMS's approach forty years ago. The term "drug," in the FDCA's "'new drug'" definition and approval requirements, the Court concluded, does *not* refer "only to the active ingredient in a drug product" but rather to "the entire product." *United States v. Generix Drug Corp.*, 460 U.S. 453, 454 (1983). In other words, a "'drug'" approved by FDA "refers to the product itself, and not simply

[1] There is no date of first licensure for the NovoLog® and FIASP® products. By operation of the Biologics Price Competition Act, the approved NDA for the FIASP® products and the approved NDA for the NovoLog® products were "deemed" to be approved BLAs as of March 23, 2020. *See* Pub. L. No. 111-148, § 7002(e)(4), 124 Stat. 119, 817 (2010); 42 U.S.C. § 262(k)(7)(D)(i).

the product's active ingredients." *United States v. Undetermined Quantities of an Article of Drug ... (Anucort HC Suppositories)*, 709 F. Supp. 511, 514–15 (D.N.J. 1987), *aff'd sub nom. Appeal of G & W Labs., Inc.*, 857 F.2d 1464 (3d Cir. 1988) (Table). Citing this long-established interpretation, FDA recently explained that for decades it "has interpreted the word 'drug' in the term 'new drug' to refer to the entire drug product and not just its active ingredient." 86 Fed. Reg. 28,605, 28,606 (May 27, 2021). FDA's approval, and the data that a manufacturer must submit in support of that approval, must be product specific in order to ensure the safety and effectiveness of the drug or biological product *as it will be used by the patient*. Approval of an active ingredient would be insufficient, since "[a]n active ingredient can have different effects on the body depending on the formulation of the drug and its route of administration (*e.g.*, topical vs. intravenous), among other things." *Id.*; *see* Laney Decl. ¶ 26.

Far from indicating any intent to reject this well-known understanding, the IRA expressly incorporates the *product-specific* approval requirement by requiring that any product subject to price controls be approved or licensed by FDA under the FDCA (or PHSA). *See* 42 U.S.C. § 1320f-1(e)(1) (incorporating § 1860D-2(e) [42 U.S.C. § 1395w-102(e)], which incorporates the definitions in § 1927(k)(2) [42 U.S.C. § 1396r-8(k)(2)], referring to drugs and biological products approved under 21 U.S.C. § 355(c) and 42 U.S.C. § 262(a), respectively); *see also Lorillard v. Pons*, 434 U.S. 575, 583 (1978) ("where words are employed in a statute which had at the time a well-known meaning … they are presumed to have been used in that sense unless the context compels to the

contrary"). FDA approves and licenses single finished drug and biological *products*; it does not approve or license aggregated families of products containing the same "active moieties" or "active ingredients." Hauda Decl. ¶¶ 9–23, 42–46. Moreover, only "single" products can serve as the "reference listed drug" or "reference product" for any other approved drug product or licensed biological product. *See* 42 U.S.C. § 262(i)(4) (explaining that "[t]he term 'reference product' means the *single* biological product licensed … against which a biological product is evaluated" (emphasis added)), *see also id.* § 262(k)(5) (noting that a "biological product ... may not be evaluated against more than 1 reference product"); 21 U.S.C. § 355(j)(2)(D) (prohibiting a generic applicant from amending its application to change its reference listed drug); 21 C.F.R. § 314.3 ("the listed drug identified by FDA [is] the drug product upon which an applicant relies in seeking approval of its ANDA"); *see also* 42 U.S.C. § 262(k)(2)(A)(i). The guidance impermissibly contorts the statutory requirements because "reference listed drugs" and "reference products" cannot be identified by active ingredient alone.

2. CMS's Approach Violates Multiple Other Express Statutory Provisions.

By imposing price controls on entire families of Novo products, CMS has not only violated the statute's express requirement that the agency set prices on no more than 10 products, it has also violated at least three other statutory mandates. These violations dramatically change the statute and undermine its express purposes.

First, CMS is imposing price controls on products that have not been on the market for the length of time required by Congress. The IRA states that products are subject to price controls only if they have been approved or licensed for at least 7 or 11 years. 42 U.S.C. § 1320f-1(e)(1)). Instead of complying with that requirement, CMS has applied "the earliest date of approval or licensure of the initial FDA application number assigned to the NDA/BLA holder for the active moiety/active ingredient …." Final Guidance § 30.1. In other words, CMS has taken the earliest date of approval for *any* product within its aggregated grouping of products and applied that date to sweep in all remaining products, even if they have not been approved for at least 7 or 11 years.

That is a dramatic substantive change to the statute. Under the IRA as written, none of Novo's FIASP® products would be subject to price controls, as none has been approved or licensed for more than the required 11 years. The FDA approved FIASP® vial and FIASP® FlexTouch® in 2017, and FIASP® Penfill® in 2018. *See* Hauda Decl. ¶ 38. Yet CMS seeks to impose price controls on all of these products merely because they share the same active ingredient.[2] That is flatly contrary to the statute and Congress's decision that CMS may not dictate prices unless and until a biological product has been licensed by FDA and on the market for at least 11 years.

[2] FDA approved a new product—FIASP® Pumpcart® Cartridge—in June 2023. Although it has not yet aggregated this product with the other insulin aspart products for price controls, CMS has asked Novo to submit data and information relevant to this product.

Second, CMS's approach violates the IRA's high-spend requirements. CMS listed the "Total Part D Gross Covered Prescription Drug Costs from June 2022–May 2023" for the aggregated family of insulin aspart products at $2,576,586,000. *See* Hauda Decl. ¶ 49. That number is incorrect, fails to adhere to the IRA's "use of data" provision, and cannot form the basis for CMS's selection of the NovoLog® and FIASP® products. Given the total Part D gross totals for other drug products and biological products, one of those products likely would have been selected instead of the aggregated NovoLog® and FIASP® products. *See id.*

Third, CMS's approach vitiates the IRA's careful differentiation between Part B drugs (physician-administered drugs and drugs self-administered through durable medical equipment in the home) and Part D drugs (other drugs administered by the patient at home). Under the statute, only Part D drugs are subject to price controls beginning in 2026; Part B drugs are exempt until 2028. *See* 42 U.S.C. § 1320f-1(a)(1)–(3). In certain instances, while Part D may cover some of a manufacturer's drug or biological products that share an active moiety or active ingredient, Part B may cover others. A drug product that is packaged in a pre-filled syringe for patient self-administration would be Part D, while a lyophilized drug product for physician (office) administration would be Part B—even though both had the same active ingredient or active moiety. Similarly, some of Novo's FIASP® products are covered primarily under Part D, and others are covered primarily under Part B. *See* Hauda Decl. ¶ 25. Under CMS's approach, however, the agency has included Part B products on the list of

products subject to price controls in 2026, directly contrary to Congress's expressed intent.

3. CMS's Approach Cannot Be Reconciled with FDA's Approval and Licensing Process.

CMS's approach creates significant tension with FDA's review and approval of products under the FDCA and PHSA in a way that Congress could not have intended. *See Morton v. Moncari*, 417 U.S. 535, 551 (1974) (courts should interpret statutes in harmony and give "effect to both if possible"). As noted above, the specific FDCA and PHSA sections cross-referenced in the IRA address FDA's approval and licensing provisions for drug and biological products. *See* 42 U.S.C. § 1320f-1(e)(1)(A)(i), (B)(i). These provisions necessarily apply on a single product-by-product basis in order to ensure safe and effective use by patients. CMS's approach is flatly at odds with FDA's decades-old approach to regulating drug and biological products. *See George v. McDonough*, 142 S. Ct. 1953, 1963 (2022) (noting that when Congress "employs a term of art," that usage suffices to "adop[t] the cluster of ideas that were attached to each borrowed word") (quoting *FAA v. Cooper*, 566 U.S. 284, 292 (2012)).

CMS's approach also has serious consequences for patients. Despite Congress's intent to gradually build a price-control program to avoid discouraging manufacturers from investing in new life-saving and life-enhancing products, CMS's approach does just the opposite, undermining the incentive structure for ensuring continued investment in research, innovation, and improvements to medicines.

It is difficult to understate the ways in which CMS's approach conflicts with the regulation of drug and biological product development and approval under the FDCA and PHSA. For example, CMS has merged the meaning of "active moiety" and "active ingredient"—which mean different things under FDA's long-standing definitions—in a way that is scientifically inappropriate and factually incorrect. *See* 21 C.F.R. § 314.3; *see also Amarin Pharms. Ir. Ltd. v. FDA*, 106 F. Supp. 3d 196, 212 (D.D.C. 2015). For instance, drug products may share an active moiety but differ in active ingredients, and active ingredients may contain multiple active moieties. As FDA has recognized, active ingredients in biological products may not be readily discernable or identifiable. *See* 42 U.S.C. § 262(k); *see also* HHS, Fiscal Year 2021: Food and Drug Administration Justification of Estimates for Appropriations Committees, at 36 ("Due to their complexity, these products' 'active ingredients' may not be precisely identifiable or may only be known to a limited extent.").

CMS's approach also undermines the value of certain regulatory exclusivities Congress created to incentivize innovation. For instance, FDA makes determinations of three-year "new clinical investigation[]" exclusivity on a product-specific basis. *See* 21 U.S.C. § 355(c)(3)(E)(iii)–(iv), (j)(5)(F)(iii)–(iv); 21 C.F.R. § 314.108. Under Congress's product-specific approach, this exclusivity is preserved because it does not last more than 7 or 11 years from the time the specific product is approved. By aggregating products, however, CMS undermines the value of exclusivity. If a manufacturer conducted new clinical investigations essential to the development and

approval of a new product with a different route of administration (one better suited to treating patients with a particular type of disease, for example), that product would be eligible for three years of exclusivity (with the ability for that manufacturer to set prices during the exclusivity period without competition). *See* 21 U.S.C. § 355(c)(3)(E)(iii)–(iv), (j)(5)(F)(iii)–(iv). Under CMS's approach, however, that new product would be subject to price controls immediately upon approval merely because it contains the same active moiety as a different product approved and licensed more than 7 years ago. That directly undermines the value of FDA's exclusivity and presents a significant disincentive to investment.

The IRA clearly cross-references FDA's product-specific approval and licensing processes, and there is no evidence that Congress intended to subject entire groupings for products with the same "active moiety" or "active ingredients" to price controls. If Congress had intended such a broad sweep, the statute would have expressly applied price controls to any product with the same active moiety or active ingredient, ensuring that all competitors were subject to the same price controls, rather than singling out specific manufacturers of an identified active moiety or active ingredient as CMS has done. The fact that Congress did not make that choice—and did not even mention active moieties or active ingredients—further confirms that Congress intended to target specific drug and biological *products*, not entire *families* of products.

4. CMS Has No Justification for Its Departure from the Statutory Requirements.

CMS's justification for aggregating products with the same active ingredient is that Congress required CMS to consider certain aggregated data when evaluating whether a product qualifies as a "Part D High Spend Drug." *See* 42 U.S.C. § 1320f-1(d)(3)(B). In particular, Congress instructed CMS to "use data that is aggregated across dosage forms and strengths of the drug" when calculating total expenditures related to a qualifying single source drug. *Id.* But Congress's instruction to use aggregated "data" for a narrow, limited purpose cannot justify CMS's decision to impose price controls on and across entire families of products. CMS has gone much further than aggregating all dosage forms and strengths of a drug when it selected every product containing insulin aspart for price controls. CMS's aggregation stretches across products—including Novo's Novolog® and FIASP® products—that are far more varied than simply differences in dosage form or strength. *See* Laney Decl. ¶¶ 23–46.

When FDA approves or licenses a drug or biological product, it does so based on its evaluation of the safety and efficacy of the specific product that will be used by a patient. Evaluation of the active moiety or active ingredient is only part of the equation. Numerous product-specific characteristics—including the product's route of administration, device presentation, manufacturing process, and inactive ingredients (in addition to dosage form and strength)—affect the safety and effectiveness, and hence approvability, of each product. As FDA has explained, it evaluates "not only the active

ingredient but also information about the drug's formulation, route of administration, labeling, inactive ingredients, bioavailability, and manufacturing processes." 86 Fed. Reg. at 28,606; 21 C.F.R. §§ 314.3(b), 210.3(b)(4) (defining a "drug product" to refer to "a finished dosage form, for example, tablet, capsule, solution, etc., that contains an active drug ingredient generally, but not necessarily, in association with inactive ingredients"). Accordingly, although the statute's "data use" provision authorizes limited aggregation for some purposes, it does not authorize aggregation by "active moiety" or "active ingredient" or permit CMS to aggregate products with different device presentations, routes of administration, or other differing conditions of use.

CMS's reading of the word "drug" renders the "use of data" instruction nonsensical. If Congress had directed that active moieties or active ingredients—rather than drugs and biological products—be subjected to price controls, there would be no dosage forms, strengths, or formulations of a drug to aggregate because the "drug" would already encompass all of the product's different dosage forms, strengths, and formulations. The same is true of the statutory instruction to establish "procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug." 42 U.S.C. § 1320f-5(a)(2). CMS's "reading is thus at odds with one of the most basic interpretive canons, that '[a] statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 556 U.S. 303, 314 (2009) (alteration omitted) (quoting *Hibbs v. Winn*, 542 U.S. 88, 101 (2004)).

In contrast, under a proper interpretation—consistent with the Supreme Court's decision and FDA's approach—the "dosage form and strength" provision is meaningful: Congress instructed CMS to aggregate data across dosage forms and strengths for the purpose of determining whether a product qualifies as a "high spend" product. Congress did not instruct CMS to subject families of products to price controls or to ignore differences between products. Congress did not empower CMS to aggregate across formulations with different device presentations, routes of administration, clinical use profiles, and other characteristics—such as the NovoLog® and FIASP® products. *See* Hauda Decl. ¶¶ 2641; Laney Decl. ¶¶ 23–46. Nor did it authorize CMS to aggregate products by "active ingredient" (or "active moiety")—terms that appear nowhere in the IRA.

When Congress intends for an agency to look to the active ingredient (or active moiety) of a drug or set of drugs, Congress says so expressly. In section 505(c) of the FDCA, for example, Congress directed FDA to determine whether a drug has the same "active moiety" as another approved drug to determine eligibility for new chemical entity exclusivity. 21 U.S.C.§ 355(c)(3)(E)(ii), (iii); *see also* 21 U.S.C. § 360bbb-4a(a)(4)(D) (grant priority review in certain circumstances for "a biological product, no active ingredient of which has been approved in any other application …"). Congress included no such provision in the IRA. CMS's regulation of more than 10 products through its aggregation of different products violates the statute's express mandates.

B. No Judicial Review Bar Applies to Prevent the Court from Striking Down CMS's Ultra Vires Statutory Rewrite.

The Administrative Procedure Act provides that a person adversely affected by final agency action is entitled to judicial review. 5 U.S.C. §§ 702, 704. Only if a statute clearly and convincingly bars judicial review is review foreclosed. *See Guerrero-Lasparilla v. Barr*, 140 S. Ct. 1062, 1069 (2020). A statute bars judicial review only if it is not "reasonably susceptible" to a "divergent interpretation." *Id.* And "judicial review remains available" when an agency has "engaged in 'shenanigans' by exceeding its statutory bounds." *SAS Inst., Inc., v. Iancu*, 138 S. Ct. 1348, 1359 (2018).

Congress did not preclude judicial review of CMS's compliance with the statutory mandate that only 10 drug products be eligible for price controls. The requirement that CMS impose price controls on no more than 10 drug products in 2026 is found in subsection (a) of 42 U.S.C. § 1320f-1. The IRA's judicial review bar extends to certain selections and determinations under subsections (b), (d), (e), and (f), but it does not cover subsection (a). 42 U.S.C. § 1320f-7. It does not include capacious language, such as barring claims "relating to" any aspect of the selection or determination process. *Cf. United States v. Dohou*, 948 F.3d 621, 626 (3d Cir. 2020) (it is relevant "when a jurisdiction-stripping provision … omits capacious phrases like 'relating to.'"). Congress knew how to bar review of the 10-drug limit but chose not to do so.

To the extent CMS argues that this Court should extend the judicial-review bar to cover subsection (a), the Court should decline. As the Supreme Court has explained,

"arguments against judicial review cannot override the text of the statute." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. 724, 733 (2022). And they certainly cannot overcome the "strong presumption in favor of judicial review of administrative action." *E.O.H.C. v. Sec'y DHS*, 950 F.3d 177, 184 (3d Cir. 2020); *see also Dohou*, 948 F.3d at 626–27 ("Before reading a statute so broadly as to strip us of the power to review an executive determination, we require clear and convincing evidence.").

Nor can CMS evade review by arguing that § 1320f-7 covers its unsupportable "active moiety" / "active ingredient" approach. The IRA does not grant CMS the power to re-define the term "drug product" or "biological product" nor the process by which such products are approved and licensed. It certainly does not insulate CMS from judicial review of its attempts to do so.

The IRA's judicial review bar applies only to CMS's application of the statutory requirements to the data and information it is authorized to collect—specifically, the agency's (1) "selection" of which (but not how many) drug and biological products should be subject to price controls, (2) "determination" of which such products are negotiation-eligible, (3) "determination" of whether products are qualifying single source drugs, and (4) "determination" of a maximum fair price. 42 U.S.C. § 1320f-7. The agency's power to "determine" or "select" which products are subject to price controls—undertaking the calculations necessary to apply the plain statutory requirements to the facts and data at its disposal—does not grant the agency the more-expansive power to redefine the applicable statutory terms against which those

determinations must be made. When Congress delegates definitional authority to an agency, it knows what to say. *See, e.g.*, 42 U.S.C. § 18022(b)(1) (instructing that "the Secretary shall define the essential health benefits …"); 42 U.S.C. § 1395w-141(f)(1)(B) (directing that "the Secretary shall define the terms 'income' and 'family size'"); 42 U.S.C. § 1395w-4(j)(1) (granting the Secretary authority to "define surgical service[]"). Congress did not authorize CMS to rewrite the IRA's underlying statutory definitions.

This understanding is reinforced by the "well-settled" presumption "favoring interpretations of statutes to allow judicial review of administrative action." *Kucana v. Holder*, 558 U.S. 233, 251–52 (2010); *see also E.O.H.C.*, 950 F.3d at 184 (same). Because "Congress legislates with knowledge of the presumption," only "clear and convincing evidence" is sufficient to "dislodge" it. *Kucana*, 558 U.S. at 252; *see also Mach Mining, LLC v. EEOC*, 575 U.S. 480, 486 (2015) (noting the government's "heavy burden" to overcome the presumption).

There is no such evidence here. Had Congress intended CMS to redefine statutory terms and insulate those definitions from judicial review, it would have (1) delegated that definitional authority to CMS and (2) expressly insulated it from review. Congress did no such thing. And for good reason: delegating unreviewable lawmaking authority to an executive agency would raise serious constitutional concerns. *See Jennings v. Rodriguez*, 583 U.S. 281, 286 (2018) ("[A] court may shun an interpretation that raises serious constitutional doubts"). It is one thing to shield from review an agency's discretionary decisions concerning how to analyze data and select *which* 10

products are subject to price controls. It is another to ignore the statutory mandate, select more than 10 products, and then defend the agency's position not on its merits but on grounds that the redefinition expands the review bars to allow the agency to escape Congress's commands. *See Amgen Inc. v. Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004) (recognizing that the scope of a judicial review bar is often "intertwined with the question of whether the agency has authority for the challenged action").

Courts have long rejected that gambit, recognizing that courts retain jurisdiction whenever an agency's action is ultra vires. "If an agency exceeds 'its statutory bounds, judicial review remains available' to curb the rogue action." *Am. Clinical Lab'y Ass'n v. Azar*, 931 F.3d 1195, 1203, 1208 (D.C. Cir. 2019) (quoting *SAS Inst.*, 138 S. Ct. at 1359); *Advanced Disposal Servs. E., Inc. v. NLRB*, 820 F.3d 592, 600 (3d Cir. 2016). That is true "[e]ven where Congress is understood generally to have precluded review." *Griffith v. Fed. Lab. Rels. Auth.*, 842 F.2d 487, 492 (D.C. Cir. 1988); *see Lepre v. Dep't of Lab.*, 275 F.3d 59, 73 (D.C. Cir. 2001); *Dart v. United States*, 848 F.2d 217, 224 (D.C. Cir. 1988). As the Supreme Court has explained, agencies' power to act is "authoritatively prescribed by Congress" and, therefore, when they act improperly or "beyond their jurisdiction, what they do is ultra vires." *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013); *see also 1621 Route 22 W. Operating Co. v. NLRB*, 825 F.3d 128, 140 (3d Cir. 2016). An agency action is ultra vires when the agency has exceeded its statutory authority, "disregarded a specific and unambiguous statutory directive," violated a statute's "specific command," or patently misconstrued the statute. *Griffith*, 842 F.2d at 493.

CMS's decision to target more than 10 drug and biological products for price controls—and to impose price controls on products that have not been approved or licensed for the period mandated by Congress—is ultra vires because it rewrites the statute's plain text and exceeds the specific, numerical cap that Congress imposed on the agency's exercise of regulatory authority. *See SAS Inst.*, 138 S. Ct. at 1355 ("Where a statute's language carries a plain meaning, the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer."); *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 328 (2014) (noting the "core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate"). This Court has both the authority and constitutional duty to require that CMS abide by the IRA's clear mandates.

II. CMS Has Violated Both the Inflation Reduction Act and the Administrative Procedure Act by Imposing New Substantive Rules.

Congress recognized the risk that CMS would deviate from the statutory requirements and, in doing so, irreparably damage the nation's drug markets and patients' access to medicine. To address that risk, the statute directs that CMS "shall implement [the IRA's price control program] for 2026, 2027, and 2028, by program instruction or other forms of program guidance." 42 U.S.C. § 1320f note; *see Kingdomeware Techs., Inc. v. United States*, 579 U.S. 162, 172 (2016) (noting that "shall" usually "imposes a mandatory duty"). By requiring CMS to proceed only by "guidance," the statute makes clear that Congress granted the agency no authority to impose new

binding requirements during that time. In short, Congress intended the agency to implement the statute as written and deprived it of any rulemaking authority.

Congress's instruction that CMS proceed only by guidance is important. Under the APA, agency guidance can have no legal consequences and no binding force and effect. *See Kisor v. Wilkie*, 139 S. Ct. 2400, 2420 (2019). In contrast, when an agency seeks to create new duties or to impose new legal obligations, it must comply with notice-and-comment rulemaking procedures. *See SBC Inc. v. FCC*, 414 F.3d 486, 495, 497 (3d Cir. 2005) (noting that legislative rules are "subject to notice and comment requirements" because they "'create new law, rights, or duties.'"); *see also Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019) (noting that when the government wishes to establish a "substantive legal standard" affecting Medicare, it must satisfy notice-and-comment obligations). To issue a valid rule, an agency "shall … publish[]" a "[g]eneral notice of proposed rule making" "in the Federal Register," and "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." 5 U.S.C. § 553(b), (c); *see also* 42 U.S.C. § 1395hh(a)(2).

Instead of complying with the IRA and the APA, however, CMS has issued binding rules in the guise of policy guidance. The agency cannot dispute that its final guidance goes far beyond the requirements imposed by the statute itself. From "beginning to end," the guidance "reads like a ukase. It commands, it requires, it orders, it dictates." *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000). And it has been applied by CMS "in a way that indicates it is binding." *Gen. Elec. Co. v. EPA*,

290 F.3d 377, 383 (D.C. Cir. 2002). Indeed, the guidance has been used to set the terms of the "agreements" that manufacturers are forced to sign. These contractual provisions, which go beyond the statute's requirements, are legislative rules subject to the APA's notice-and-comment requirements. *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1053–54 (D.C. Cir. 1987); *see also Nat'l Ass'n of Psychiatric Treatment Ctrs. for Child. v. Weinberger*, 658 F. Supp. 48, 54 (D. Colo. 1987) (holding APA applied to agency attempt to make "prescriptive changes in overall contents of all participation agreements … [that] amount[ed] to policy changes of significant import").

The guidance also goes far beyond merely "interpreting" the IRA. As noted above, CMS has redefined "drug product" and "biological product"—departing from their settled meanings—so as to materially expand the number of products subject to price controls. *See Pa. Dep't of Human Servs. v. United States*, 897 F.3d 497, 505 (3d Cir. 2018) (explaining that interpretive rules "do not add language to or amend language in the statute"). Similarly, the statute states in clear terms that products subject to marketed generic or biosimilar competition "shall not be subject to the negotiation process." 42 U.S.C. § 1320f-1(c); *see id.* § 1320f-1(e)(1)(A)(iii), (B)(iii) (citing 21 U.S.C. § 355(j); 42 U.S.C. § 262(k)); 21 C.F.R. § 314.3 (defining "commercial marketing"). Yet CMS's guidance changes the statutory test by purporting to authorize CMS to engage in a "holistic" analysis to determine when competition is sufficiently "meaningful" that the agency deems competition to be "bona fide." Final Guidance at 72 & § 30.1; *see also City of Arlington*, 569 U.S. at 307 ("Where Congress has established a clear line, the

agency cannot go beyond it[.]"). The same is true of many of CMS's other additions that it has treated as having binding and substantive consequences, including its decision to abandon the IRA's definition of a "manufacturer" in favor of newly defined terms—"primary" and "secondary" manufacturers—that do not appear in the statute, *see* Final Guidance § 40, and its decision to both restrict and expand the types of information that manufacturers may or are required to submit as part of the "negotiation" process. *See* Hauda Decl. ¶ 55; Final Guidance App. C.

If Congress wanted to grant CMS authority to impose new obligations on manufacturers without complying with notice-and-comment requirements, it would have said so expressly, or at least directed CMS to promulgate rules to govern the first three years of the program. But for good reason, it did not. Instead, Congress directed the agency to proceed through guidance alone. 42 U.S.C. § 1320f note. Congress's command that CMS proceed by guidance means the agency must refrain from imposing substantive obligations that stray from the statute's plain text.

III. The Inflation Reduction Act's Unprecedented Drug-Pricing Provisions Are Constitutionally Invalid.

If the Court vacates CMS's actions—striking down CMS's unlawful aggregation and preventing it from imposing price controls on Novo products—it may be able to avoid reaching the constitutional claims raised in Novo's complaint. But if complete relief is not granted to Novo on those grounds, this Court will be forced to consider the IRA's grave constitutional problems and the reality that its provisions depart from

any price-control statute that has ever previously been upheld against constitutional challenge. Through its unprecedented provisions, Congress has committed egregious violations of the Constitution's separation-of-powers, due process, and free speech guarantees by delegating unfettered power to CMS to set prices, removing the judiciary's ability to ensure that the CMS-imposed prices are not arbitrary or confiscatory, and requiring manufacturers to mouth the government's preferred message about "fairness" on pain of severe penalties. Each individual constitutional violation warrants this Court's intervention; the simultaneous removal of multiple layers of constitutional protections demands it. *See Seila Law LLC v. CFPB*, 140 S. Ct. 2183, 2198, 2202 (2020).

A. The Inflation Reduction Act Unlawfully Eliminates Accountability by Combining a Sweeping Delegation of Power with Other Constitutional Violations.

The Constitution provides overlapping safeguards to ensure democratic accountability and to protect individual liberty. The structure of the federal government—separating powers in different branches—is "designed to preserve the liberty of all the people," *Collins v. Yellen*, 141 S. Ct. 1761, 1780 (2021), and to ensure that both Congress and the Executive remain accountable to the citizenry, *Free Enter. Fund v. PCAOB*, 561 U.S. 477, 496 (2010); *Seila Law*, 140 S. Ct. at 2202. The Fifth Amendment's Due Process Clause reinforces those aims by prohibiting the government from depriving a person of "life, liberty or property" without "due process of law." Nathan S. Chapman & Michael W. McConnell, *Due Process as Separation of Powers*, 121

Yale L.J. 1672, 1758–60 (2012). Rooted in principles dating back to the *Magna Carta,* due process safeguards both legislative independence and individual rights by protecting against arbitrary administrative actions, *Murray's Lessee v. Hoboken Land & Imp. Co.*, 59 U.S. (18 How.) 272, 276 (1855), and by ensuring an affected party's baseline procedural right to be heard, *Mathews v. Eldridge*, 424 U.S. 319, 333 (1976). Similarly, the First Amendment is "fundamental" to our "constitutional system" by maintaining "the opportunity for free political discussion," so "that the government may be responsive to the will of the people and that changes may be obtained by lawful means." *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 269 (1964).

The IRA's novel price-setting scheme strips away all three of these constitutional safeguards in a bid to avoid public accountability for its infringement of private rights. Even if one of the violations could be tolerated individually, the "combined" nature of the violations creates "a new situation" that cannot stand. *Free Enter. Fund*, 561 U.S. at 483–84; *Seila Law*, 140 S. Ct. at 2202.

1. The Statute Violates Separation of Powers

It is well settled that "Congress may not constitutionally delegate its legislative power to" any other branch of government and must always "lay down by legislative act an intelligible principle to which" the official with delegated authority "is directed to conform." *Touby v. United States*, 500 U.S. 160, 165 (1991); *see also Marshall Field & Co. v. Clark*, 143 U.S. 649, 692 (1892). The Constitution reflects the lessons of "hard experience 'that abandonment of separated powers led directly to the loss of

accountable, impartial government, which, in turn, led inevitably to the loss of due process and individual rights.'" *Egan v. Del. River Port Auth.*, 851 F.3d 263, 278 (3d Cir. 2017) (Jordan, J., concurring).

The Supreme Court's modern non-delegation doctrine cases are often summarized as applying an "intelligible principle" test. *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (plurality). But controlling precedent requires more than merely considering whether Congress has articulated an intelligible principle—that is, some ascertainable legislative standard to which the agency's decision-making must conform. Context matters, including the nature of the delegation, the degree to which the delegation endangers private rights, and the history of similar regulation. *See A.L.A Schechter Poultry Corp. v. United States*, 295 U.S. 495, 541 (1935) (striking down statute that was "without precedent"). The "degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 475 (2001). When a statute involves a broad grant of delegated authority, Congress must stay within the bounds of precedent. It cannot strip away multiple layers of constitutional protections, create a "novel structure," *Free Enter. Fund*, 561 U.S. at 496, and concentrate "significant governmental power" in an agency "accountable to no one." *Seila Law*, 140 S. Ct. at 2203.

The IRA fails these constitutional requirements both because of the breadth of authority granted to CMS and the lack of constitutional safeguards necessary to protect the important public interests and private rights at stake. Most significantly, the IRA

delegates to CMS power to set prices with no intelligible principle to guide and constrain the agency's price-setting decisions. Apart from an already low ceiling price, there is no legal standard to govern CMS's price-setting decision and no limits on how low (or confiscatory) a price CMS might dictate. The statute defines "maximum fair price" not by reference to any standard of fairness or reasonableness, but merely as the "price negotiated"—that is, the price unilaterally dictated by CMS. *See* 42 U.S.C. § 1320f(c)(3). Moreover, although the IRA includes a list of "factors" that the agency must "consider," *id.* § 1320f-3, CMS has conceded that the statute "does not specify how the [agency] should determine" what price to impose "or to what degree each factor should be considered." Final Guidance § 60.3. In short, the IRA grants CMS unconstrained authority to impose whatever prices the agency might select in its unfettered discretion.

That alone constitutes an unlawful delegation of legislative power. The power to control the price at which private parties sell their products raises significant risks of unfair regulatory targeting. While Congress may delegate authority for an agency to perform the calculations necessary to determine an appropriate price, Congress must articulate the underlying standards to ensure that prices are constitutionally permissible. The requirement that Congress set forth "ascertainable standards" is essential, as "the existence of an absolute and uncontrolled discretion in an agency of government vested with the administration of a vast program" creates "an intolerable invitation to abuse." *Holmes v. N.Y. City Hous. Auth.*, 398 F.2d 262, 265 (2d Cir. 1968).

The lack of an intelligible principle is made worse by Congress's decision to withdraw judicial review of CMS's price-setting decisions. *See* 42 U.S.C. § 1320f-7; *United States v. Garfinkel*, 29 F.3d 451, 458–59 (8th Cir. 1994) (Judicial review "is a factor weighing in favor of upholding a statute against a nondelegation challenge."). That removal of judicial protection—another "significant and unusual" deviation from standard mechanisms for ensuring accountability, *Free Enter. Fund*, 561 U.S. at 506—heightens the nondelegation concerns because "judicial review perfects a delegated-lawmaking scheme by assuring that the exercise of such power remains within statutory bounds." *Touby*, 500 U.S. at 170 (Marshall, J., concurring). By stripping away review, Congress has provided mere suggestions for CMS to consider, not requirements to which the agency "is directed to conform." *Touby*, 500 U.S. at 165; *cf. United States v. Touby*, 909 F.2d 759, 768 (3d Cir. 1990) (noting that "[j]udicial review is the usual vehicle by which executive action is tested to insure that the will of Congress has been obeyed").

In short, Congress must provide adequate standards "such that a court [can] ascertain whether the will of Congress has been obeyed." *Skinner v. Mid-Am. Pipeline Co.*, 490 U.S. 212, 218 (1989). Stripping away this "layer" of insulation from accountability "makes a difference." *Free Enter. Fund*, 561 U.S. at 495. With no intelligible principle, and with the further violations discussed below, the IRA is unconstitutional.

2. The Statute Violates Due Process

The IRA's price-setting scheme compounds its separation-of-powers violations by eliminating essential due process protections. The Fifth Amendment's Due Process Clause provides that government may not deprive anyone of "life, liberty or property" without "due process of law." U.S. Const. amend. V. As relevant here, due process constrains the government in two fundamental ways:

First, due process ensures that the executive acts "as authorized by law." *Murray's Lessee*, 59 U.S. at 276; *Hamdi v. Rumsfeld*, 542 U.S. 507, 589 (2004) (Thomas, J., dissenting) ("the Due Process Clause requires … that our Government must proceed according to the 'law of the land'—that is according to written constitutional and statutory provisions"). The Supreme Court has repeatedly emphasized this core feature of our Constitution: due process protects "the individual against arbitrary action of government." *Wolff v. McDonnell*, 418 U.S. 539, 558 (1974); *see also Honda Motor Co. v. Oberg*, 512 U.S. 415, 434 (1994) (due process protects against "arbitrary deprivations of liberty or property"). Rather than ensure that CMS acts in line with statutory requirements, the IRA invites arbitrary action by withdrawing judicial review from the price-setting regime's core features, including choosing what prices to set. *See Oberg*, 512 U.S. at 421 ("our analysis in this case should focus on [the law's] departure from traditional procedures"); *see also Bowles v. Willingham*, 321 U.S. 503, 521 (1944) ("where Congress has provided for judicial review after the regulations or orders have been made effective it has done all that due process under the war emergency requires").

Second, due process requires that the government's deprivation of rights be accompanied by certain "procedural protections characteristic of judicial process." Chapman & McConnell, 121 Yale L.J. at 1679; *Mathews*, 424 U.S. at 335. The Supreme Court's decision in *Oberg* reflects this protection. There, the Court held that a provision in the Oregon Constitution limiting (but not prohibiting) judicial review of the amount of punitive damages awarded by a jury was inconsistent with due process. *See Oberg*, 512 U.S. at 418. "[The] abrogation of a well-established common-law protection against arbitrary deprivations of property raises a presumption that its procedures violate the Due Process Clause." *Id.* at 430.

On this front too, the IRA falls short. Despite the substantial rights at play, the IRA abrogates the ordinary common-law protection of judicial review and even forecloses administrative review of CMS's actions. *See* 42 U.S.C. § 1320f-7. There can be no doubt that the private interests endangered by the IRA are substantial. *See Mathews*, 424 U.S. at 335. The IRA threatens Novo's rights to sell its products at market-based prices and undermines Novo's investments and research programs. *See* Hauda Decl. ¶¶ 67–69, 75–77; *see also Old Dearborn Distrib. Co. v. Seagram-Distillers Corp.*, 299 U.S. 183, 192 (1936) (noting the "well-settled general principle that the right of the owner of property to fix the price at which he will sell it is an inherent attribute of the property itself" and protected by the Fifth Amendment). Novo has relied on the promise of future sales—and the ability to charge market-based prices—when developing and patenting its innovative drugs and biological products, including investing in products

that never made it to market. *See King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995). The IRA interferes with Novo's rights by requiring Novo to provide "access" to its products on terms that Novo would never voluntarily accept. *Cedar Point Nursery v. Hassid*, 141 S. Ct. 2063, 2072 (2021); *Horne*, 576 U.S. at 361–62.

Exacerbating these weighty concerns, the risks of an erroneous deprivation are very high. *See Mathews,* 424 U.S. at 335. When government controls prices, it must include adequate procedures to "safeguard against imposition of confiscatory rates" and to ensure that private property owners ultimately receive "a fair and reasonable return on investment." *Michigan Bell Tel. Co. v. Engler*, 257 F.3d 587, 594–96 (6th Cir. 2001). Yet the IRA includes no procedures to protect against arbitrary or confiscatory pricing. There is no guarantee that CMS will set a price that will allow Novo to obtain any return on its investments—let alone a just and reasonable one. *See id.* at 595 n.4 (explaining that due process requires adequate procedures to ensure a "fair and reasonable" price, not just the "possibility" that the regulator might not impose a confiscatory price).

For Novo's products, the IRA imposes an across-the-board ceiling price that is already very low, 42 U.S.C. § 1320f-3(c)(1)(C), (b)(2)(F), directs CMS to aim for "the lowest" price, *id.* § 1320f-3(b)(1), and includes no floor or standards to ensure a reasonable return. Nor is it any consolation that Novo might hypothetically increase prices in the non-Medicare/non-Medicaid markets. A party cannot be "required to subsidize their regulated" products with "revenues generated from unregulated services." *Michigan Bell*, 257 F.3d at 594–96 (citing *Brooks-Scanlon Co. v. R.R. Comm'n*,

251 U.S. 396 (1920)). Where, as here, a statutory program "provides *no process* whatsoever," the government has a "glaring problem" that "alone" compels the conclusion that the program is unconstitutional. *Schepers v. Comm'r, Ind. Dep't of Corr.*, 691 F.3d 909, 915 (7th Cir. 2012).

The statutory process does not even provide a meaningful opportunity for a hearing or any opportunity to respond to the evidence on which the agency relies. *See Mathews*, 424 U.S. at 333. Due process requires the government to provide regulated parties with access to the evidence against them and an "opportunity to meet it." *Id.* at 348; *see Townley v. Heckler*, 748 F.2d 109, 114 (2d Cir. 1984) (agency violated due process by relying on evidence that it did not give claimant opportunity to rebut). But the IRA does not require CMS to disclose to Novo the evidence on which it will rely in setting the "maximum fair price" for Novo's different products. Although Novo is permitted to make a counteroffer in response to CMS's "initial offer," 42 U.S.C. § 1320f-3(b)(2)(B), *see also id.* § 1320f-3(b)(2)(C)(ii), (e), the IRA does not require CMS to do anything with this counteroffer, beyond "respond[ing] in writing to" it. *Id.* § 1320f-3(b)(2)(D). CMS need not provide a reasoned explanation for its response or take any steps to show that it is acting reasonably. That empty procedure is insufficient and falls far short of minimum constitutional requirements. *See Ohio Bell Tel. Co. v. Pub. Utils. Comm'r*, 301 U.S. 292, 302 (1937); c*f. Connecticut v. Doehr*, 501 U.S. 1, 4 (1991) (explaining that law authorizing deprivation of property without prior notice or hearing or extraordinary circumstances violates due process). "The core of due process is an

opportunity to be heard at a meaningful time and in a meaningful manner." *Frein v. Pa. State Police*, 47 F.4th 247, 257 (3d Cir. 2022). The IRA bars any such opportunity.

The removal of these traditional procedural safeguards is especially harmful in the context of setting prices. Appellate courts have repeatedly struck down legislative schemes that do not include sufficient procedures to "adequately safeguard[] against confiscatory rates, and therefore, ensure[] a constitutional rate of return." *Michigan Bell*, 257 F.3d at 592–93; *see also Guar. Nat'l Ins. Co. v. Gates*, 916 F.2d 508, 512 (9th Cir. 1990) (invalidating Nevada law freezing insurance rates because it provided no "mechanism to guarantee a constitutionally required fair and reasonable return"). Adequate process when determining the prices of drugs is paramount because of the important public interests and private rights at stake. If government-imposed prices are too low, the public will face shortages, a lack of innovation, and other collateral consequences, and the private entity will suffer confiscatory rates. *See In re Permian Basin Area Rate Cases*, 390 U.S. 747, 769–70 (1968) (prices imposed by the government must be "just and reasonable." (citing *Fed. Power Comm'n v. Nat. Gas Pipeline Co.*, 315 U.S. 575, 586 (1942))).

The IRA's lack of any intelligible principle combined with the lack of adequate procedures is especially problematic because the agency here is not only a regulator but also a self-interested market participant with an incentive to "act for 'selfish' or 'arbitrary' reasons." *Rice v. Vill. of Johnstown*, 30 F.4th 584, 589–91 (6th Cir. 2022) (quoting *Washington ex rel. Seattle Title Tr. Co. v. Roberge*, 278 U.S. 116, 122–23 (1928)). CMS is not merely setting a price; it is setting a price for Medicare beneficiaries that it

has promised to insure. As courts have long recognized, an absence of impartiality is most apparent when a decision-maker has a "pecuniary interest in the outcome" of a proceeding. *Tumey v. Ohio*, 273 U.S. 510, 535 (1927); *see also Withrow v. Larkin*, 421 U.S. 35, 47 (1975). As the nation's largest payor for prescription drugs, there is no reason to expect that CMS will protect the private rights of manufacturers or even the interests of patients over its own financial interests. *See, e.g., Ne. Hosp. Corp. v. Sebelius*, 657 F.3d 1, 20 n.1 (D.C. Cir. 2011) (Kavanaugh, J., concurring) (noting HHS's "apparent policy of paying out as little money as possible" even "in derogation of law").

3. The Statute Violates the First Amendment.

Further preventing lawful accountability, the IRA requires manufacturers to say that they "agree" to "negotiate" and that the price unilaterally imposed by CMS is the "maximum fair" price for their drug and biological products. 42 U.S.C. § 1320f-2(a). Although Novo does not agree with these inaccurate characterizations, the statute forces Novo to parrot the government's viewpoint or else face massive penalties. That is unconstitutional. The First Amendment bars the government from "compel[ling] a person to speak its own preferred messages." *303 Creative LLC v. Elenis*, 600 U.S. 570, 586 (2023). As courts have long held, "[g]overnment action that requires stating a particular message favored by the government violates the First Amendment right to refrain from speaking." *Miller v. Mitchell*, 598 F.3d 139, 151 (3d Cir. 2010).

The IRA's "involuntary affirmation of objected-to beliefs" is a textbook example of unconstitutionally compelled speech. *Janus v. Am. Fed'n of State, Cnty., & Mun. Emps.,*

Council 31, 138 S. Ct. 2448, 2464 (2018). By selecting Novo's six products, CMS forced Novo to sign an "agreement" with the agency or face crippling penalties for failing to do so. The IRA requires that the "agreement" state that Novo "agree[s]" to engage in a "negotiation" that will result in CMS imposing a "maximum fair price." 42 U.S.C. § 1320f-2(a). Because the IRA compels Novo to enter this "agreement," the statute forces Novo to espouse the government's preferred views.

CMS cannot fix this constitutional problem by slapping a disclaimer on the compelled speech. The template agreement that manufacturers must sign includes a made-for-litigation provision: "In signing this Agreement, the Manufacturer does not make any statement regarding or endorsement of CMS' views .... Use of the term 'maximum fair price' and other statutory terms throughout this Agreement reflects the parties' intention that such terms be given the meaning specified in the statute and does not reflect any party's views regarding the colloquial meaning of those terms." CMS, Medicare Drug Price Negotiation Program Agreement Template, at 4. But, as the Third Circuit has explained, the fact that a government body "can issue a general disclaimer along with the [required] recitation does not erase the First Amendment infringement at issue here …. Otherwise, the state may infringe on anyone's First Amendment interests at will, so long as the mechanism of such infringement allows the speaker to issue a general disclaimer." *Circle Sch. v. Pappert*, 381 F.3d 172, 182 (3d Cir. 2004). No matter how the agency might back track, the First Amendment violation is baked into

the IRA, which requires manufacturers to "agree[]" to the misnamed "maximum fair price." 26 U.S.C. § 5000D(a)–(b).

Novo would never willingly describe the IRA or CMS's price-setting decisions in these terms. *See* Hauda Decl. ¶ 70. Novo does not agree that the program is voluntary, let alone a "negotiation." Novo must either sign the agreement, incur a crippling "excise tax" penalty, or withdraw all of its products from 50% of the nation's healthcare markets. Novo may not negotiate the terms of the "agreement," and the government has asserted that it can change those terms at any time. *See* Hauda Ex. E §§ II(e), IV(b). Moreover, Novo does not agree that whatever price CMS imposes is the "maximum fair" price, or even *a* fair price. *See* 42 U.S.C. §§ 1320f-2, 1320f-3; Hauda Decl. ¶¶ 53, 70. As noted above, Novo objects to aggregating multiple different products for price controls. Moreover, the IRA mandates a price ceiling—40% to 75% of the drug's average net price to non-federal purchasers. *See* Hauda Decl. ¶¶ 68–69; *see also* 42 U.S.C. § 1320f-3(c)(1)(C), (b)(2)(F). Between 40 and 75 percent of a *net* price is already a very low price (as the net price reflects all discounts and rebates). Whatever the price CMS imposes on Novo's six products, Novo would not voluntarily characterize it as a "maximum fair price." *See* Hauda Decl. ¶ 70.

Laws that compel speech are subject to strict scrutiny and must be narrowly tailored to serve a compelling governmental interest. *Nat'l Inst. of Fam. & Life Advocs. v. Becerra* (*NIFLA*), 138 S. Ct. 2361, 2371 (2018); *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 188 (3d Cir. 2005). The IRA fails that test. The government has no valid interest

in forcing Novo to serve as a "courier" for its preferred viewpoint, preventing open debate about the fairness of the price CMS chooses to impose. *Wooley v. Maynard*, 430 U.S. 705, 717 (1977). Nor is the IRA narrowly tailored. Compelling speech is not necessary to set drug prices, and much less burdensome alternatives "are obvious." *U.S.W., Inc. v. FCC*, 182 F.3d 1224, 1238 (10th Cir. 1999). If the government wants to impose price controls, there are no valid reasons manufacturers should not be allowed to express publicly their dissatisfaction with that price. *See NIFLA*, 138 S. Ct. at 2376. Under the First Amendment, the IRA's "compulsion ... plainly violates the Constitution." *Janus*, 138 S. Ct. at 2464.

B. No Comparable Statute Has Ever Been Upheld.

The IRA is unlike any price-setting scheme Congress has ever created. The "lack of historical precedent" for the IRA's price-control program is a "telling indication" that the statute is constitutionally invalid. *Free Enter. Fund*, 561 U.S. at 505–06. Novo is aware of no other statute that grants such sweeping power to an agency, strips away procedures necessary to protecting private rights, eliminates judicial review, and includes a forced-speech requirement. Simply put, the IRA is an "historical anomaly." *Seila Law*, 140 S. Ct. at 2202.

Consider rate-setting regimes for energy transmission. Rates must be "just and reasonable," 16 U.S.C. § 824d, and statutory procedures limit the authority of the Federal Energy Regulatory Commission ("FERC") to set rates. *See* 16 U.S.C. §§ 824d, 824e, 825*l*; *Mobil Oil Expl. & Producing Se. Inc. v. United Distrib. Cos.*, 498 U.S. 211, 218

(1991) (noting use of notice-and-comment rulemaking to "revise the old gas pricing system"). An entire body of law has developed to ensure adequate review of FERC's rate-setting authority so that it is not used in an arbitrary, discriminatory, or otherwise unconstitutional manner. *See In re Permian Basin*, 390 U.S. at 769–70. And judicial review is available to ensure that FERC complies with due process, the statutory standard, and the procedural requirements of the governing statute and the APA. *See, e.g.*, 15 U.S.C § 717r; 16 U.S.C. § 825*l*.

Similarly, when Congress undertook to regulate coal prices in the 1930s, it did not give the Coal Commission carte blanche to drive prices as low as it pleased. Congress instead required that any "maximum price" established for a mine must "yield a fair return on the fair value of the property." *Sunshine Anthracite Coal Co. v. Adkins*, 310 U.S. 381, 397 (1940). Congress also provided that "maximum prices must be fixed at a uniform increase above minimum prices so that in the aggregate they will yield a reasonable return above the weighted average total cost of the district." *Id.*

Even the most controversial laws enacted during wartime—a nadir for the protection of private rights—contained more robust protections than the IRA. For example, Congress enacted the Emergency Price Control Act of 1942, in the middle of World War II, seeking to "create[e] a nationwide system of price controls." *Cmty. Hous. Improvement Program v. City of New York*, 59 F.4th 540, 545 (2d Cir. 2023). The statute directed the Office of the Price Administrator to set such "maximum prices as in his judgment will be generally fair and equitable and will effectuate the purposes of th[e]

Act" when prices had risen or were expected to rise to certain levels. Emergency Price Control Act of 1942 ("EPCA"), Pub. L. No. 77-421, § 2(a), 56 Stat. 23, 24. Even though EPCA was a "war emergency measure," *Adamo Wrecking Co. v. United States*, 434 U.S. 275, 290 (1978) (Powell, J., concurring), it contained multiple layers of protections to protect accountability that are missing in the IRA. For example, EPCA provided for judicial review of "all questions of law, including the question whether the Administrator's determination is supported by evidence." *Yakus v. United States*, 321 U.S. 414, 437 (1944). It included a robust administrative process, where parties could protest price controls and receive an "administrative hearing." *Id.* at 436. And EPCA provided ascertainable standards to govern the Administrator's price-setting decisions, requiring that they be "fair and equitable" and "effectuate [the statute's] purposes." EPCA § 2(a).

In contrast, the Supreme Court has invalided statutes that, like the IRA, confer "virtually unfettered" discretion on the executive to control large parts of the economy. *Schechter*, 295 U.S. at 542. In *Schechter*, the Court struck down the Recovery Act's delegation to the President to create codes of "fair competition," including wage controls, for the poultry industry. Although the Recovery Act set forth "general aims" to guide the President's discretion, Congress had not "itself established the standards of legal obligation" and had thus failed to "perform[] its essential legislative function." *Id.* at 530, 541–42. Contrasting this scheme with the Federal Trade Commission's regulation of "unfair competition," the Court emphasized the lack of "judicial review

to give assurance that the action of the [executive] is taken within its statutory authority" and the absence of "appropriate administrative procedure" to ensure due process. *Id.* at 532–33, 541. Similarly, in *Panama Refining Co. v. Ryan*, the Court invalidated a statute authorizing the President to ban petroleum shipments in excess of state quotas. 293 U.S. 388, 418 (1935). Although the statute contained a "general outline of policy," including "remov[ing] obstructions to the free flow of interstate and foreign commerce" and "favor[ing] the fullest possible utilization of the present productive capacity of industries," those vague directives did not amount to a "standard or rule." *Id.* at 417–18.

C. The IRA's Constitutional Violations Cannot Be Excused.

The IRA's constitutional problems cannot be excused by pretending that manufacturers have voluntarily embraced price controls by virtue of their continued participation in the Medicare and Medicaid programs. Private parties cannot consent to a violation of the Constitution's structural protections, the IRA does not provide manufacturers with any meaningful choice, and forcing manufacturers to forfeit their constitutional rights violates the unconstitutional conditions doctrine.

Parties cannot waive the Constitution's structural protections. Parties cannot accept structural constitutional violations—such as separation of powers violations—"by consent." *Commodity Futures Trading Comm'n v. Schor*, 478 U.S. 833, 850-51 (1986); *see also Stern v. Marshall*, 564 U.S. 462, 483 (2011). Accordingly, even if participation in the federal healthcare programs were voluntary, that does not save the

IRA. More broadly, the government cannot take over an entire segment of the interstate market and then coerce manufacturers into forfeiting their constitutional rights in order to participate in that market. *See Horne*, 576 U.S. at 365 (rejecting argument that party can be forced to decide between exiting a market and forfeiting its constitutional rights); *cf. S.-Cent. Timber Dev., Inc. v. Wunnicke*, 467 U.S. 82, 98 (1984) (explaining that a state cannot leverage its role as a market participant to evade constitutional limits on its regulatory powers). The government's power to set prices when it is procuring products for itself—and the principle that parties can choose freely whether to contract with the government—does not apply when the government is exercising regulatory powers in a market that it "dominates." *Sanofi Aventis,* 58 F.4th at 699. The Constitution would be a particularly thin parchment barrier if the government could wall off half the nation's interstate market and make access to that market depend on forfeiting constitutional rights. *See U.S. Term Limits, Inc. v. Thornton*, 514 U.S. 779, 829 (1995) (noting that "[t]he Constitution 'nullifies sophisticated as well as simple-minded modes' of infringing on constitutional protections" (quoting *Lane v. Wilson*, 307 U.S. 268, 275 (1939))).

Participation in the IRA is coercive, not voluntary. The Supreme Court has long held that actions taken under threat of severe economic coercion are not voluntary. In *Union Pacific Railroad Co. v. Public Service Commission*, for instance, the Court concluded that government could not "impose an unconstitutional burden by the threat of penalties worse than [that burden] in case of a failure to accept it, and then to declare

the acceptance voluntary." 248 U.S. 67, 70 (1918). Economic "duress" negates any purported "choice" between compliance and "grave penalties" because it is "practically impossible not to comply with the terms of the law." *Id.* Likewise, in *United States v. Butler*, the Court recognized that a "regulation is not in fact voluntary," and the "asserted power of choice is illusory," where Congress used "coercion by economic pressure" "to induce to surrender [of a private party's] independence of action." 297 U.S. 1, 70–71 (1936); *see also Carter v. Carter Coal Co.*, 298 U.S. 238, 289 (1936) (concluding that purportedly voluntary "agreement" to participate in coal regulation program was "coerce[d]" and "lack[ed] the essential element of consent" because it was backed by provisions imposing substantial taxes for noncompliance, and observing that "[o]ne who does a thing in order to avoid a penalty does not agree").

The IRA is additionally coercive because manufacturers cannot lawfully withdraw from its price-control program for a period of 11 to 23 months. During that period, if a manufacturer does not "agree" to the government-imposed price, it is immediately subject to a draconian excise "tax" that no manufacturer could afford to pay. *See Thompson v. Deal*, 92 F.2d 478, 484 (D.C. Cir. 1937) (holding that program that required parties to sign an agreement with the government under threat of a "confiscatory" tax "not designed to raise revenue" was coercive). The "tax" applies while the manufacturer participates in Medicare, Medicaid, or the IRA-created "manufacturer discount program." 26 U.S.C. § 5000D.

Perhaps recognizing that participation under the statute is not voluntary, CMS has proposed a workaround, purporting to allow manufacturers to withdraw from its pricing program in 30 days. *See* Final Guidance §§ 40.1–40.2, 40.5–40.6. But that workaround was developed "only in the course of litigation," reflecting a "*post hoc*" tactic "by an agency seeking to defend past [congressional] action against attack." *Valancourt Books, LLC v. Garland*, 82 F.4th 1222, 1237 (D.C. Cir. 2023). It is not binding and, because it was not promulgated through regulations, it cannot change the statute's legal requirements. In any event, as courts have long held, "an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regul. Grp.*, 573 U.S. at 328. Rewriting a statute is prohibited, even if a rewrite could avoid serious constitutional concerns. *See Stern*, 564 U.S. at 478.

The IRA violates the unconstitutional conditions doctrine. Even if Novo had a meaningful choice, the IRA would still violate the Constitution under the unconstitutional conditions doctrine. That doctrine "is based on the proposition that government incentives may be inherently coercive." *Koslow v. Pennsylvania*, 302 F.3d 161, 174 (3d Cir. 2002). The Supreme Court has "repeatedly rejected the argument that if the government need not confer a benefit at all, it can withhold the benefit because someone refuses to give up constitutional rights." *Koontz v. St. Johns River Water Mgmt. Dist.*, 570 U.S. 595, 608 (2013) (collecting cases); *see also United States v. Am. Library Ass'n*, 539 U.S. 194, 210 (2003). The government may not condition government benefits to achieve "a result which [it] could not command directly." *Speiser v. Randall*, 357 U.S.

513, 526 (1958); *Frost v. R.R. Comm'n*, 271 U.S. 583, 593–94 (1926) ("inconceivable" that the "guarantees embedded in the Constitution" could be "manipulated out of existence.").

When Congress seeks to require the surrender of constitutional rights in return for a government benefit, there must be a *nexus* and *rough proportionality* between the benefit provided and the constitutional right to be relinquished. *Koontz*, 570 U.S. at 612; *cf. Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc.*, 570 U.S. 205, 214–15 (2013) (the Government cannot "leverage funding to regulate speech outside the contours of the program itself"). The IRA program does not impose any lawful "condition" because its obligations are not a general prerequisite for all manufacturers to participate in Medicare and Medicaid. Instead, they are a unique burden imposed only a small subset of targeted manufacturers. *Cf. Valancourt*, 82 F.4th at 1233 (finding no "voluntary exchange" when property owners received no "incremental benefit" by forgoing their right). Moreover, there is no nexus and rough proportionality between the constitutional rights surrendered and the right for Novo to participate in Medicare and Medicaid. To the contrary, Congress guaranteed that manufacturers like Novo would have no choice but to "agree" to the IRA's obligations by tying those obligations to the manufacturer's ability to have *any* of its drugs covered by federal healthcare programs. Because a manufacturer must either be "all in" or "all out" of Medicare and Medicaid, a manufacturer has no ability to withdraw a "selected drug" if CMS's "maximum fair price" is unfairly low without withdrawing its entire portfolio of medicines from nearly

half the market for prescription drugs. Congress knew that forcing a manufacturer to withdraw all its products from federal healthcare programs would be economic suicide (to say nothing of the harms to patients)—and not a real option.

In *National Federation of Independent Business v. Sebelius* (*NFIB*), 567 U.S. 519, 578, 581 (2012), the Supreme Court evaluated circumstances that closely parallel this case and concluded that forcing an entity to either accept new conditions or withdraw from Medicaid was no real choice. In *NFIB*, Congress pressured states to accept a Medicaid expansion by threatening the withdrawal of all Medicaid funding. Although the Medicaid expansion may have been "in form voluntary," *Frost*, 271 U.S. at 593, the Court held that "[t]he threatened loss of over 10 percent of a State's overall budget … is economic dragooning that leaves the States with no real option but to acquiesce in the Medicaid expansion," *NFIB*, 567 U.S. at 582. That financial threat was "a gun to the head." *Id.* at 581. And while Congress "styled" the expansion as part of Medicaid, it was effectively a "new health care program" because states "could hardly anticipate" that Congress would "transform" Medicaid so "dramatically." *Id.* at 584–85.

The same is true here. Congress is pressuring manufacturers to agree to CMS-imposed prices with no procedural review by threatening to kick the manufacturer and *all of its products* out of Medicare and Medicaid. And as in *NFIB*, the "choice" here is illusory. In both instances, Congress could impose its mandates via a nominal "choice" only because Congress knew that the regulated entity would have no real choice. *See id.* at 581–82, 587. If anything, the IRA involves even more coercive "economic

dragooning." Whereas federal Medicaid funding comprised 10% of the states' budgets in *NFIB*, Medicaid and Medicare account for nearly half of the prescription drug market. *See Sanofi Aventis*, 58 F.4th at 699. If states, with all their resources, are vulnerable to financial coercion, private entities are even more vulnerable to the "ruinous" "loss of federal funds." *Doe v. Univ. of Scis.*, 961 F.3d 203, 213 (3d Cir. 2020).

Like the Medicaid expansion in *NFIB*, it is indisputable that the IRA dramatically "transform[s]" the federal healthcare programs. 567 U.S. at 583. Manufacturers that signed up to participate in those programs—and invested billions of dollars in developing and distributing drugs that treat and cure beneficiaries—never signed up for the IRA. And companies could "hardly anticipate," *id.* at 584, that Congress would repudiate market-based pricing for prescription drugs, especially as reflected in the Medicare Part D "noninterference" clause, *see* 42 U.S.C. § 1395w-111(i). Congress went from prohibiting the government from strong-arming manufacturers to requiring CMS to do so. Any "asserted power of choice" here is "illusory." *Butler*, 297 U.S. at 71. Forcing a regulated entity to choose between two unacceptable outcomes—"the rock and the whirlpool"—is no choice at all. *Id.* at 72 (quoting *Frost*, 271 U.S. at 593); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 513 (1996) (plurality opinion).

CONCLUSION

The Court should enter summary judgment in Novo's favor and vacate CMS's unlawful actions. In the alternative, it should declare the IRA's drug-pricing provisions to be unconstitutional.

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Respectfully submitted,

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